# DESIGN FOR A POPULATION STUDY OF EXPOSURE OF U.S. ADULT SMOKERS TO CIGARETTE SMOKE &

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# WHY STUDY CIGARETTE SMOKE **EXPOSURE?**

Olganese smoking causes king cancer, heart disease emphysisma and other technics diseases

WHY

To set in the development and assessment of fature ordinary personal person

# WHAT HAS BEEN DONE?

Machine Smoking Date - Provide chemical smoke constituent measures in a staticardizati, reproductive fashion (19 to February Cast Germanous (FED) exercised organization of Separategian (Section (1905) exercised organization of Separategian (Section (1905) exercised (1915) and Castal replaced.

A g. Masser M. 1887 System 1927, System 6, 1988, Geogradus a invest Concerns: Typically single blomarker, based on small, non-representative samples, marries not consistent among studies

# WHAT NEEDS TO BE DONE?

Directly evaluate and be constituents or their metabolites in appropriate.

- blant to sale out burn attend of effect
- Contral reference to a see in opposition studies. Select representative postulation sample. Exercise the restaurable between two services of exposure and blomastigate of feet.

# WHAT WE PROPOSE

emokans):

anokans or secretary (inc.) categories to generate beening data for
extract exposure differs for segments of FTC for detecting whether
emokans):

A pilot study is being conducted to determine the less bility of the large scale. Total Exposure Stroly and vistemples estimates of unrainity for eample size determination

# **EXCLUSION CRITERIA**

- Persons less than 21 years of age (Pouto id age valification required Pregnant or massing women. Use of notatine containing factors is now tobacco products other than manufactors of greates during part 3 months.
- ECG)
  Participants on other dimea' studies or blood dengra/receivant
  Tobacco wideshy or CRO analysis and immediate lambs

# **EXCLUSION CRITERIA SMOKERS**

- Consumption of less than 1 manufactured eigensite of a specified brand per day for a matchism of 12 months. Switched brands during fast 3 months prior to accomment.
- Switchind branchs during last 3 months in the ris emplained than the specified and price of the specified and afficient than the specified range with in the task 3 months before envolved the or is different priced of operation often than their preferred brand or a value of monetium. If the of dely consumption during the test three months procedure.

# **EXCLUSION CRITERIA** NON-SMOKERS

#### **COMPLEXITIES OF** SAMPLING U.S. SMOKERS

For the Total Exposure Study (TES) to be representative of U.S. adult introdes of as lar yield (FTC) caregories, the sample must relact important demographic characteristics, such as regions:

- gender recerebuildity education ercorts

#### PILOT STUDY DESIGN

- Single conto: Independent contract research organization (CRO) Independent contract research organization (CRO) Hoostly adult enclars of lower jeld FTO Tot dispassible (6.5 m gis) Non-armiting control group Fearshill), study, 60 actual simulation 60 adult non-armiting control group Six malein (6.5 doubt enclars).

- procured.

  To establish the validity of the datage corregist for the TES.

  To distance that that and times reclyding learning for bonnature of exposure and bornature of effect.

  To compute the bi-archive sole apposure and the bromatics of effect on reclyding one of the dataget.

# PILOT STUDY **PARTICIPANTS**



### **MEASUREMENTS**

- Questionnaire, diary, weekly survey
  - Characterise population, amoking behavior of the expressive metading environmental tob
- Biomarkers of exposure manufir rikumitir senoke exposure
- Biomarkers of effect

# **QUESTIONNAIRE**

- Glastadence responses to folsecon smoke and other exponents that could provide the country of th

- ongme-edusary.

  Exemus self-reported exposure to departite smoke; of others (strengts and destron).

  Delamines excluded use, and physical activity.

  Allow modeling of exposure and exemination of outliers.

**BIOSAMPLES: PILOT** 

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#### SUMMARY

- Design of Total Exposure Study is excepted
- Pilot study is underway
- Data or suppositions are invited as input into this design

#### REFERENCES

Byrd G.D., et al. A Burther study of FTG yield and absoline absorption in smokent Psychopheromecology: 698, 38: 231-239

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